



THE ORTHOPEDIC CENTER, P.A.

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Scoliosis
Sports Medicine
Trauma
Club Feet
Hip Dysplasia
Limb Discrepancy

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Orthopedic Research Society
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November 30, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket #: 97N-484S

Dear Ladies & Gentlemen:

I would like to state my opposition to listing **allograft** bone as a medical device. **Allograft** bone has been around for decades, and its safety has clearly been demonstrated many times over. The risks and benefits of **allograft** are always explained to patients when consent is performed, and the patients are very well aware of the risks and benefits of receiving **allograft** bone.

It is my firm belief that by changing the rules and making **allograft** a medical device that it will seriously curtail the availability of **allograft** and hurt the general public's health. I have always been a very strong advocate for my patients and their well being, and anything such as this proposal that can harm the ability of the media/ community to provide the maximum care for our patients I will be opposed to.

Sincerely,

Mark A. Rieger, M.D.

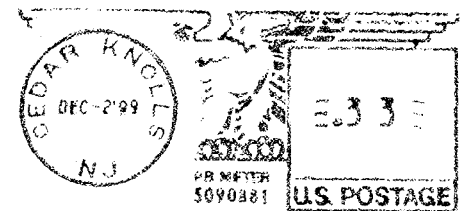
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